

## **REMARKS**

Claims 1-17 are pending in this application. Applicants have amended claims 6-9 and 11-12 to make minor editorial changes. No new matter has been added. Applicants have also amended claim 4 to better define the subject matter claimed. No new matter has been added.

The Examiner rejected claims 1-3 and 13-17 under 35 USC 103(a) as being unpatentable over Richards U.S. Patent No. 6,507,829 and Kapp U.S. Patent Pub. No. 2002/0010595. The Examiner also rejected claims 4-12 under 35 USC 102(b) as being anticipated by Richards. Applicants respectfully traverse these rejections.

Applicants' claim 1 recites a computer-assisted method of processing a drug information source where the drug information source comprises at least one instance of drug rule content. Each instance of drug rule content comprises at least one drug rule. The method includes creating a drug rule syntax, detecting at least one instance of drug rule content from a drug information source, parsing drug rule elements from at least one identified instance of drug rule content into the drug rule syntax and retaining associations between those drug rule elements that form a drug rule. A subset of the drug information source is processed into syntax-parsed drug rules.

Independent claim 13 recites a method for processing a drug information source where the drug information source is characterized by metadata including verbatim data and at least one instance of drug rule content. Each instance of drug rule content includes at least one drug rule. The method includes creating a drug rule syntax, extracting metadata from the drug information source, extracting verbatim adverse event data from the drug information source, identifying at least one instance of drug rule content from the drug information source, mapping terms from verbatim data to a reference source, parsing drug rule elements from at least one identified instance of drug rule content into the drug rule syntax and retaining associations between those drug rule elements that form a drug rule. The drug described by the drug information source is characterized by the set comprising the syntax-parsed drug rule elements, the mapped terms and the metadata.

Applicants' invention is directed to a fixed predicate logic structure in which to embed information that is usually in text format. This involves a generic and evolvable predicate logic structure into which drug information rules can be included when originally expressed in text format. Applicants' invention identifies each of the elements/classes/classifications/categories, etc. which need to have a dictionary into which verbatim terms can be put and classified in a logical way. Applicant's invention uniquely identifies, e.g., sees 'before' or 'prior' to mean that the drug referenced is a previously taken medicine, not one being taken now, or lets the operator select from nominated text where it goes in the rule structure. The same term can be included in any of these categories and the present invention keeps them arranged in a logical context. The result is a way to take text and make a series of logically usable information. This creates machine-understandable and consistent rules (predicate logic) for drug information and drug safety.

The combination of elements defined by applicants' claims is neither disclosed nor suggested by Richards or Kapp, viewed alone or in combination.

Richards is directed to creating a dictionary from various terms for the same or similar things and is a way of classification from verbatims, e.g., adverse event reports, which are an example of medical text. Moreover, Richards' syntax has nothing to do with logical syntax, but is only a way to rank. In Richards, the use of "and" and "not" are only used as a way to disqualify highly ranked terms. Additionally, Richards uses iterative refinement and other techniques that only show a way of applying weight factors (e.g., how often 'migraine' and 'headache' are together). That, too, is not the claimed invention.

The Examiner admits that Richards does not explicitly teach using drug rules, and turns to Kapp to supply the missing piece. The Examiner contends that Kapp teaches the use of drug rules at paragraph 13, lines 1-5. Applicants respectfully disagree. While Kapp teaches storing information in a database on the usage, dosing and contra-indications for a plurality of drugs, any discussion of 'drug information' is just standard text data. In Kapp, his database is merely a text-

filled table. See, e.g., Kapp Figs. 14, 21 and 22. That is not the claimed drug rule syntax and associated steps of applicants' methods recited in claims 1 and 13. Kapp, like Richards, discloses nothing related to the logic of drug data.

Even if the resulting combination suggested by the Examiner included all the limitations of claims 1 and 13, the cited references provide no evidence of a motivation to combine their disclosures so as to arrive at the claimed invention. The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination. The Examiner has pointed to no disclosure in Kapp, the alleged evidence of such a motivation, which would have motivated a person of ordinary skill in the art to combine Kapp with Richards.

Thus, claims 1 and 13 are patentable over the cited references and should be allowed. This logic also disposes of the rejections of claims 2-3 and 14-17, which depend directly from claims 1 and 13.

Regarding the rejection of claims 4-12 under 35 USC 102(b) as being anticipated by Richards, applicants also traverse this rejection with respect to claim 4, as amended.

Amended claim 4 recites a computer-assisted method of processing a drug information source where the drug information source comprises at least one instance of adverse event content. Each instance of adverse event content comprises at least one adverse event characterization. The method comprises detecting at least one instance of adverse event content from a drug information source and parsing at least one adverse event characterization from at least one detected instance of adverse event content. A subset of the drug information source is processed into at least one parsed adverse event characterization. The at least one adverse event characterization comprises quantitatively explicit information.

Adverse event content is very different from adverse event terms (such as rash and headache). It refers to information in tables or in context lists that allow new information. Similarly, characterization of adverse events refers to qualities such as frequency in a clinical trials, quite different from the text names.

Richards neither discloses nor suggests the required combination of elements. In particular, Richards contains no disclosure or suggestion that the adverse event characterization comprises quantitatively explicit information. Richards is directed to extracting information from text only. See Richards, col. 5, lines 35-40 and col. 6, lines 20-29. That is not the claimed invention.

Thus, claim 4 is patentable over the cited reference and should be allowed. This logic also disposes of the rejections of claims 5-12, which depend directly or indirectly from claim 4.

In view of the above, each of the claims in this application is in condition for allowance. Accordingly, applicants solicit early action in the form of a Notice of Allowance.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 597932000320**.

Respectfully submitted,

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